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10/717,528	11/21/2003	Josephine Sara Turner	2509 US	8423
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GEORGE A. SEABY			LOVE, TREVOR M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,528	<b>Applicant(s)</b> TURNER ET AL.
	<b>Examiner</b> TREVOR M. LOVE	<b>Art Unit</b> 4131

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08e) Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

**ACTION STATUS SUMMARY**

1. Claims 1-17 are pending.
2. The use of the trademark HYDROTHANE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.
  - a. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

**APPLICANT'S INVENTION**

1. Applicant's invention is directed to a two component interpenetrating polymer network wound dressing material comprising a hydrophilic first component, and biocompatible second component, which is cross-linked.

***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-6 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 of copending Application No. 10/815715. Although the conflicting claims are not identical, they are not patentably distinct from each other because the main difference between the claims is the additional step of aging. It is well known in the art that if one ages polymer network, more crosslinking will be allowed to occur.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 5-10, and 13-17 are rejected under 35 U.S.C. 112 2nd paragraph as being indefinite.

a. Instant Claims 2 and 6, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i. Claim 2 recites the limitation "a hydrophilic polymer and a an elastomer" in lines 1-2 of claim 2. It is unclear whether "a hydrophilic polymer" and "and a an elastomer" refer to entities that are being newly introduced, or the components of claim 1. As the claim currently reads, there is insufficient antecedent basis for this limitation in the claim.

ii. Claim 6 recites the limitations "gelatin" and "HYDROTHANE" in the first and second line of claim 6 respectively. There is insufficient antecedent basis for this limitation in the claim.

b. Instant Claims 5-10 and 13-17 contains the trademark/trade name HYDROTHANE. Where a trademark or trade name is used in a claim as a

limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydrophilic polyurethanes and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Instant Claims 1-4 and 11-12 are rejected under U.S.C. 102(a) and (e) as being obvious over U.S. Patent number 6,331,578.

a. Instant Claim 1 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over U.S. Patent Number 6,331,578 (Turner et al.). Turner discloses a method of making an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the reaction mixture of the above components also has a crosslinker (Turner, column 22, lines 55-58), and the mixture forms a membrane (Turner, column 9, lines 11-14).

b. Instant Claim 2 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over Turner for the reasons set forth for Instant Claim 1, wherein Turner further discloses that the hydrophobic component is a siloxane (Turner, column 11, line 36).

c. Instant Claim 3 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over the arguments set forth for Instant Claim 2, wherein Turner further discloses that the membrane, which is an elastomeric polymer network, has the ability to expand and retract based on the environment (Turner, column

10, lines 56-60), which has the same function as the three-dimensional open mesh described in the Instant Specification (page 8, lines 20-24).

d. Instant Claim 4 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over the arguments set forth for Instant Claim 2, wherein Turner further discloses that the hydrophilic component is polyethylene oxide (Turner, column 11, lines 43-46), and the hydrophobic component as a siloxane (Turner, column 11, lines 13-15).

e. Instant Claim 11 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over Turner. Turner discloses an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the reaction mixture of the above components also has a crosslinker (Turner, column 22, lines 55-58), and the mixture forms a membrane (Turner, column 9, lines 11-14).

f. Instant Claim 12 is rejected under 35 U.S.C. 102(a) and (e) as being unpatentable over the arguments set forth for Instant Claim 11, wherein Turner further discloses that the membrane, which is an elastomeric polymer network, has the ability to expand and retract based on the environment (Turner, column 10, lines 56-60), which meets the limitations of the three-dimensional open mesh described in the Instant Specification (page 8, lines 20-24).

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. Instant Claims 5-10 and 13-17 are rejected under U.S.C. 103(a) as being obvious over U.S. Patent number 6,331,578 in light of U.S. Patent number 4,983,702 and 4,966,953.
  - g. Instant Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claim 1 in further view of Shikinami. Turner teaches the disclosure as set forth above but fails to teach polyurethane or gelatin. Shikinami, while teaching a polyurethane gel, discloses that both polyurethane and gelatin are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikinami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin since Shikinami clearly states that they are viable options for a hydrogel.
  - h. Instant Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claim 1, wherein Turner further discloses that the hydrophilic component's constituents may be any crosslinkable

water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). Though Turner does not directly teach gelatin, it can be seen from the discussion of Instant Claim 5, namely Shikinami, that it would be obvious to one of ordinary skill in the art to use gelatin as said hydrophilic component, but Turner further shows that a methacrylate, which can include of gelatin, would be even better. Therefore, it would be obvious to one of ordinary skill in the art to create said methacrylate by adding methacrylic anhydride to the gelatin which would inevitably create even greater crosslinking within the gelatin. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36).

- i. Instant Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claim 6, wherein Turner further discloses the use of a third component as a cosolvent in the reaction to achieve the required chemical potential (Turner, column 7, lines, 61-64). Turner fails to directly teach that the cosolvent as DMSO, however, it is disclosed in U.S. Patent number 4,983,702, which discusses a crosslinked siloxane-urethane polymer contact lens, that "compatibility can often be improved by the use of compatibilizing aprotic solvents, such as...dimethyl sulfoxide" (Mueller, column 7, lines 27-29). Thus it would be obvious to one of ordinary skill in the art to add DMSO to the components taught by Turner, in order to improve compatibility.

j. Instant Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claims 1 in further view of Shikinami. Shikinami, while teaching a polyurethane gel, discloses that both polyurethane and polyvinyl alcohol are polymer compounds which can form hydrogels (Shikinami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and polyvinyl alcohol since Shikinami clearly states that they are viable options for a hydrogel.

k. Instant Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claim 9, wherein Turner further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). From the discussion of Instant Claim 9, it is shown that it would be obvious to one of ordinary skill in the art to use polyvinyl alcohol as said hydrophilic component, but Turner further shows that a methacrylate would be even better. Therefore, it would be obvious to one of ordinary skill in the art to add a methacrylating agent to the polyvinyl alcohol to create even greater crosslinking within the polyvinyl alcohol. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36). Again, is there something that Turner fails to teach that makes this a 103 and not a 102? ((This is dependent from claim 9 which is under 103(a)

I. Instant Claim 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner as set forth for Instant Claim 11, in further view of Shikinami. Shikinami, while teaching a polyurethane gel, discloses that polyurethane, gelatin, and polyvinyl alcohol are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikinami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin or polyvinyl alcohol since Shikinami clearly states that they are viable options for a hydrogel. Turner further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). It would be obvious to one of ordinary skill in the art to use gelatin or polyvinyl alcohol as said hydrophilic component, but Turner further shows that a methacrylate would be even better. Therefore, it would be obvious to one of ordinary skill in the art to add methacrylic anhydride to the gelatin to create even greater crosslinking within the gelatin or polyvinyl alcohol.

NO CLAIM IS ALLOWED.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres or Cecilia Tsang can be reached at 571-272-0867 or 571-272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L ANDRES/  
Supervisory Patent Examiner, Art Unit 4131

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